APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,748	12/21/2001	David H. Mack	018547-034810US	9678

			EXAMINER
33494	7590	04/05/2004	SIEW, JEFFREY

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ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)
		10/028,748	MACK ET AL.
Office Action Summary		Examiner	Art Unit
		Jeffrey Siew	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on <u>01 April 2004</u>.

2a) ☐ This action is **FINAL**.   2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-10,12-19,25-34,36-43 and 49-53* is/are pending in the application.

    4a) Of the above claim(s) *54 &55* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-10,12-19,25-34,36-43 and 49-53* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *21 December 2001* is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a) ☐ All b) ☐ Some * c) ☐ None of:

      1. ☐ Certified copies of the priority documents have been received.

      2. ☐ Certified copies of the priority documents have been received in Application No. _____.

      3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage
application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
    Paper No(s)/Mail Date *12/23/02*.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1.   I.D.S. filed 12/23/02 has been resigned and submitted with this action. The I.D.S.

although signed, was not initialed.

Election/Restrictions

2.   Claims 54 & 55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b)

as being drawn to a nonelected invention , there being no allowable generic or linking claim.

Election was made **without** in response filed 1/21/04.

Double Patenting

3.   The nonstatutory double patenting rejection is based on a judicially created doctrine
grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or
improper timewise extension of the "right to exclude" granted by a patent and to prevent possible
harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.
Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686
F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA
1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
       A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to
overcome an actual or provisional rejection based on a nonstatutory double patenting ground
provided the conflicting application or patent is shown to be commonly owned with this
application. See 37 CFR 1.130(b).
       Effective January 1, 1994, a registered attorney or agent of record may sign a terminal
disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37
CFR 3.73(b).

       Claims 1-10,12-19, 25-34,36-43,49-53 are rejected under the judicially created doctrine

of obviousness-type double patenting as being unpatentable over claims 1-50 of U.S. Patent No.

6,420,108. Although the conflicting claims are not identical, they are not patentably distinct

from each other because claims 1-50 of US 6,420,108 are drawn to the method and product of

displaying a mark at X,Y displaying information in response to user input which represents a

species of the genus computer method and product claims of the instant application which are

drawn to displaying a mark.

The response filed 1/21/04 has been considered. The response states that they will

file a terminal disclaimer when other issues of patentability are resolved. As no terminal

disclaimer or argument have been filed, the double patenting rejection is maintained.

Claim Rejections - 35 USC § 103

4.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in
> section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are
> such that the subject matter as a whole would have been obvious at the time the invention was made to a person
> having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the
> manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the

claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c)

and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4.   Claims 1-10,12-19, 25-34,36-43,49-53 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Lockhart et al (WO97/27317 21 July 1997) in view of Zhao et al (Gene Vol.

156 pp. 207-213 1995).

Lockhart et al teach a method of detecting nucleic abundances or concentrations (e.g.

expression levels) between two or more samples (see whole document esp. abstract). They teach

the simultaneous monitoring of the expression of a multiplicity of genes using perfect match

probe and mismatch probes (see page 5,12,47 & esp. 49-50). They teach that expression

monitoring would be useful for both drug safety and toxicology screenings (see page 230) and

monitoring various genes in response to defined stimuli such as drugs (see page 22). They teach

that monitoring of gene expression may be performed using a computer system running a

software program that includes computer code incorporating analysis of hydridization intensities

of the screens(see page 90 & Figure 6-8). They teach a method of comparing expression level

using the hybridization intensities between the perfect match and mismatch probes (see page 93-

101 & Figure 9-10B). They compare the hybridization intensity difference and ratio of the

perfect match and mismatch probes with a threshold. The values NPOS, NNEG and LR are

calculated for each pair of probes. The analysis is repeated to calculate the average of the

differences. They teach that oligonucleotide pairs that show the greatest differential hybridization

between two samples can be identified by sorting the observed hybridization ratio and difference

values. Based on identified oligonucleotide pair sequences, a gene can be searched for in

sequence databases such as GENBANK (see page 128-9). They also display the results in a

graph showing differential expression between samples (see Figures 16-17).

Lockhart et al do not teach presenting expression level information by displaying on a

first axis representing the expression level in a first sample, displaying on second axis

representing the expression level in the second axis and displaying a mark relative to the two

axes and inputting and receiving information associated with sequence.

Zhao et al teach bioimaging analyzer system to compare the expression profiles of thousands of genes cDNAs simultaneously . They teach a high density cDNA filter analysis in which expression profiles of 2505 cloned human brain cDNAs (genes) were monitored (see whole document esp. Abstract). A quantitative analysis of the filter is performed using Fuji Bioimaging Analyzer BAS2000 System and automated quantification program AutoQuant. The final part is sequence analysis in which each clone is characterized by homology search in the GENBANK nucleotide Sequence Database (see page 208 & Figure 1). They applied the system for the comparative analysis of expression profile of the human cDNAs in brain. The expression profiles were illustrated on graphs by comparing the their scores from two tissues with Microsoft Excel (Microsoft) on a Macintosh personal computer(see page 210-211 and fig. 3). A mark for each gene is positioned relative to the expression levels in the two different samples. Although the reference is silent to the teaching of "code", it was well known and commonly practiced that Microsoft Excel (see page 211) is a software product containing code used to generate graphs. Through the use of this code, Zhao et al generated the graphs depicted in Figure 3 to compare the expression level of two different samples. Moreover, the computer used was a Macintosh computer(see page 211) as depicted in Figure 1. Although the reference is silent to the teaching of processor, memory and display, the personal computer inherently contains a display, microprocessor and memory in the form of RAM, ROM and hard disk.

One of ordinary skill in the art would have been motivated to display the comparative expression levels of genes as in Zhao et al's to Lockhart et al's analysis technique in order to compare the gene expression between two different samples. Zhao et al's display format allows easy visualization of the many different expressions of genes between two samples. It would have been prima facie obvious to construct a graph with an axis representing the gene expression in one sample and another axis representing the gene expression in a second sample in order to compare the differential gene expression between the different samples.

Moreover, one of ordinary skill in the art would have been motivated to apply a third axis to Zhao et al display format in order to further compare the expression level in a third sample. It would have been advantageous to use a 3D format to compare three samples at the same time so that comparisons would be visually easier to interpret and would be performed simultaneously. It would have been prima facie obvious to apply a third axis to Zhao et al's display format in order to analyze more information at the same time.

Moreover, it was well known in the art at the time the invention was made to input into computer to receive information from display screen. It would have been prima facie obvious to input into Zhao et al's computer to derive data of the expression level from the display.

5. The response filed 1/24/04 has been fully considered and deemed not persuasive. The response states that at the time of producing the graph Zhao et al did not know the sequence of cDNA sequences used in the probes. First the claims do not limit as to when the sequence of clones is determined. Second Zhao et al determine information in detecting differential expressed cDNAs between fetal and adult. As the claims read broadly on any information, the art rejections over Zhou et al and Lockhart et al are maintained. (see page 211 & Figure 3).

SUMMARY

6.   No claims allowed.

CONCLUSION

7.   Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Jeffrey Siew who can be reached at 571-272-0787. The e-mail

address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-

mail system nor should official papers be transmitted through this route. The examiner is on flex-

time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach

the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on

(571)272-0782.

Any inquiry of a general nature, matching or filed papers or relating to the status of this

application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose

telephone number is (571)272-0534.

Papers related to this application may be submitted to Group 1600 by facsimile

transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

Mall 1. The faxing of such papers must conform with the notice published in the Official

Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center FAX is (703)-872-9306.

JEFFREY SIEW
PRIMARY EXAMINER

April 1, 2004